DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: OP-1 Implant
Docket No.: 02E-0147

FEB 24 2003

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,258,494, filed by Stryker Corporation, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for OP-1 Implant, the medical device claimed by the patent.

The total length of the regulatory review period for OP-1 Implant is 3,627 days. Of this time, 3,485 days occurred during the testing phase and 142 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: November 14, 1991.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on November 14, 1991.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: May 29, 2001.

   The applicant claims May 25, 2001, as the date the premarket approval application (PMA) for OP-1 Implant (PMA HO10002/A01) was initially submitted. However, FDA records indicate that PMA HO10002/A01 was submitted on May 29, 2001.

3. The date the application was approved: October 17, 2001.

   FDA has verified the applicant's claim that PMA HO10002/A01 was approved on October 17, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: James F. Haley, Jr.
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